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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,589	12/26/2001	Seiji Ohno	217577US0CONT	9443

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ART UNIT	PAPER NUMBER
1624	

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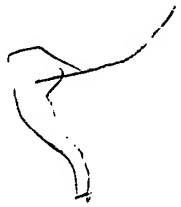
Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.	Applicant(s)
10/025,589	Ohno et al
Examiner	**Group Art Unit**
JM Ford	1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 12-26-01 ; 3-30-02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1—11, 14—22, 26 and 31—40 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☒ Claim(s) 22 is/are allowed.

☒ Claim(s) 1—11, 14—21, 26 and 40 is/are rejected.

☐ Claim(s)____ is/are objected to.

☒ Claim(s) 31—39 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

The claims in the application are now claims 1-11, 14-22, 26 and 31-40.

Claim 1 is rejected under 35 USC 112, 2nd and 1st paragraph, as a result of the use of aryl, heteroaryl and aroyl. What is intended by these terms? Where is the representative support in the specification?

Judge Smith noted may different definitions for aryl in the footnotes of In re Sus, 134 USPQ 301. It therefore, becomes necessary for applicants to indicate in the claims what they intend by aryl. Heteroaryl, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that step the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heterocyclic term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Heterocyclic is a huge area of Chemistry; heteroaryl completely overshadows the pyrimidine of formula I.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic groups for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes claim to have potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20

year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that is works, I claim it, is not proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, and Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,4,etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heteroaryl applied by applicant, has no idea where the hetero atoms are in this unknown ring.

What are the hetero atoms?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification?

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed. Variable A is acceptable.

The ultimate utility here is some sort of vague inhibiting activation of N-type calcium channel, unspecified, pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heteroaryl products many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expressions in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does to include the source of the starting material for the rings which applicant now claims, one must be able to tell from simple reading of the claim what it does and not encompass.

Why? Because that compound claim precludes others from making, using or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, column 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. vs. United States, 193 U.S.P.Q. 449, "claims measure the invention and resolution of the invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "we have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11 at 15.

Heteroaryl is too broad stated in claim 1, see In re Wiggins, 178 U.S.P.Q. 421.

The heterocyclic expression includes adjacent O/S combinations that are unstable. The claimed expressions do not tell the reader what the hetero atoms are, or where they are in the ring.

The claim cannot be completely searched, here, until we know what heteroaryl means.

In this connection, the USPTO only recognizes: C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heteroaryl is not just a substituent; it is a whole body of art, larger than the pyrimidine claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

What is the purpose of the "proviso" in the middle of page 4 of the amendment of March 28, 2002? Is prior art being written around in claim 1?

Variable B_2, at the top of page 5 of the amendment of March 28, 2002, indicates "contains a hetero atom"

What hetero atom did applicants have in mind? Further, "contains" is an open term.

In the last line of this page 5 (claim 1) one finds: "aroyl". What is intended?

Claims 2—5 and 7—10 are rejected as being dependent on a rejected claim.

Claims 6 and 11 are rejected for the reasons claim 1 was in regard to "aryl". However, claims 6 and 11 are, also rejected as a result of "substituted"

There is too much picking and choosing form the air with nothing to go on but "substituted", The Supreme Court objected to the open breadth of substituted in a claim in 1928: Corona v., Dovan, 1928 C.D. 253; 276 U.S. 358.

Claims 14—16, 18, 20, 26 and 40 are rejected as being dependent on a rejected claim.

Claims 17, 19, 21 are rejected for the reasons noted in the rejection of claim 1, above.

Claim 17, 19 and 21 are rejected as being dependent on a rejected claim, and for the open nature of "substituted". Substituted with what? Note Corona vs. Dovan 1928 USSC; 276 U.S. 358 (35 U.S.C. 112, 1st and 2nd paragraph) what is it? Where is it supported?

Claim 22 is allowed.

The recent utility guidelines set by the USPTO require applicants to meet the requirements as stated in Brenner vs. Manson in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that Nelson vs. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

MPEP 806.05(h) provides for restriction. A broad disclosure of utility, as in the cited claims 31—39 cannot be deemed in compliance with 35 U.S.C. 101 and 35 U.S.C. 112 first paragraph.

The PTO has amended the guidelines to clarify "specific utility". The court focused on the fact that the applicant failed to identify a "specific utility" in Brenner vs. Manson.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Applications and National Phase Application under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should limit the method claims to a "specific utility".

Claim 36 lists many diseases in a vague manner that are notoriously difficult to treat; that would require considerable proof, and is not limited to one.

Claims 31—39 are subject to a restriction requirement to one believable utility.

Claim 31 is too broad and indefinite to be considered one claim 31 is some sort of laboratory list, that does not meet the real world of commerce test for a utility.

Claims 31—39 are all too vague and multiple to be considered an acceptable method claim.

Restriction is proper where the compounds as claimed may be used for more than one purpose, the claims become evidence claims to that allegation. See MPEP 806.05(h).

The use needs to be believable, that applicants pick.

Applicants are required to pick one believable use.

MPEP 806.05(h) provides for restricting out the method claims, altogether, if applicants do not elect one specific real world disease. This is consistent with 37 CFR 1.475 in 371 application, and PCT Rule 13.2 in PCT applications.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

This is in regard to the Japanese acknowledgement national applications. No 371 application is found.

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624

Ford:mv
June 3, 2002